Decision Memo for Ambulatory Blood Pressure Monitoring (CAG-00067R)

Decision Summary

This memorandum announces our intention to change CIM Section 50-42 to clarify that a physician is required to perform the interpretation of the data obtained through ABPM, but that there are no requirements regarding the setting in which the interpretation is performed.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

TO: Administrative File: CAG-00067R
Ambulatory Blood Pressure Monitoring

FROM:

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RE: Coverage Decision Memorandum for Ambulatory Blood Pressure Monitoring

DATE: January 16, 2003

This memorandum serves the purpose of correcting potentially misleading language in Coverage Issues Manual Section 50-42, Ambulatory Blood Pressure Monitoring. Section 50-42 currently states that the 24-hour measurements collected by an ambulatory blood pressure monitor "…are stored in the device and are later interpreted at the physician's office." However, the reference to the physician's office can be misleading. The intent of our policy was not that ABPM data be interpreted specifically in the setting of a physician's office, but rather that the data be interpreted by a physician, without specification of the setting.

Background

An ambulatory blood pressure monitor (ABPM) is a non-invasive device used to measure blood pressure (BP) in 24-hour cycles. The device consists of a portable sphygmomanometer attached to a recording device. The ABPM is fitted to and removed from the patient by a trained technician. The sphygmomanometer inflates at predetermined times, generally every 30 minutes, and the BP recorded at each inflation are stored. The patient performs his/her normal activities while wearing the monitor.

This is distinct from the current standard measurement and assessment of blood pressure, i.e., clinic measurement, where random isolated measurements are taken during office visits (occurring during daytime hours). Both ABPM and clinic measurements are, however, conducted through the supervision of a physician (ABPM is not a self-monitoring device). A physician is required to allow for the adequate evaluation of data from an ABPM. The patient is instructed on how to wear the device, but it is up to the physician to interpret the collected data. The physician accomplishes this by uploading the data onto a computer where device-specific programs are used to categorize and analyze the measurements. ABPM differs from self-measurement (home monitoring), as the latter is performed by the patient who takes his or her own BP readings.

FDA Status

Companies manufacturing ABPM devices have obtained clearance for marketing of these devices under the Food and Drug Administration's (FDA) 510(k) process. The predicate device was a normal non-invasive BP monitor.

History of Medicare Coverage

Effective April 1, 2002, CMS began covering ABPM devices for those patients with suspected white coat hypertension. This coverage policy is listed in the Coverage Issues Manual Section (CIM) 50-42. The manual section defines suspected white coat hypertension as "1) office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; 2) at least two documented blood pressure measurements taken outside the office which are <140/90 mm Hg; and 3) no evidence of end-organ damage."

CIM Section 50-42 also states that BP measurements stored in an ABPM device "…are later interpreted at the physician's office." It has been brought to our attention by CMS staff that this language could be misinterpreted to mean that coverage only applies if the physician interprets ABPM measurements in his/her office. However, the intent of our policy was not that ABPM data be interpreted specifically in the setting of a physician's office, but rather that the data be interpreted by a physician, without specification of the setting. We have also received a letter from the American College of Cardiology in support of this position. Therefore, we will amend the CIM language to reflect this clarification.

Decision

This memorandum announces our intention to change CIM Section 50-42 to clarify that a physician is required to perform the interpretation of the data obtained through ABPM, but that there are no requirements regarding the setting in which the interpretation is performed.

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